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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. No. 04-204-JJF **REDACTED VERSION**

DOT'S MEMORANDUM IN SUPPORT OF ITS MOTION *IN LIMINE* TO PRECLUDE EVIDENCE REGARDING COMPROMISE NEGOTIATIONS AND THE TIMING OF DOT'S ASSERTION OF ITS DETAILED NON-INFRINGEMENT AND INVALIDITY CONTENTIONS, REGARDING THE BONE FILLER PATENTS-IN-SUIT (U.S. PATENT NOS. 6,241,734 AND 6,613,054)

Defendants Disc-O-Tech Medical Technologies, Ltd. and Disc Orthopaedic Technologies, Inc. ("DOT") respectfully submit this motion in limine, pursuant to Rules 408 and 403 of the Federal Rules of Evidence, to preclude Kyphon Inc. ("Kyphon") from presenting evidence or argument at trial relating to compromise negotiations as to U.S. Patent Nos. 6,241,734 and 6,613,054 ("bone filler patents"), or relating to the timing of DOT's assertion of detailed non-infringement and invalidity contentions.

PRELIMINARY STATEMENT

REDACTED

REDACTED

NATURE AND STAGE OF THE PROCEEDINGS

This is an action by Plaintiff Kyphon against Defendants DOT for infringement of U.S. Patent Nos. 4,969,888 ("the '888 patent"), 5,108,404 ("the '404 patent"), 6,235,043 B1 ("the '043 patent"), 6,248,110 B1 ("the '110 patent"), 6,241,734 B1 ("the '734 patent") and

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REDACTED

6,613,054 B1 ("the '054 patent"). DOT has counterclaimed against Kyphon for declaratory judgments of non-infringement and invalidity of the patents-in-suit. Kyphon has moved for summary judgment of infringement of the '404, '888, '734 and '054 patents. DOT has moved for summary judgment of non-infringement of the '404, '888 and '043 patents and invalidity of the '404 and '888 patents. On April 19, 2005, Special Master Vincent Poppiti heard argument on all of these motions, as well as on claim construction issues. A pretrial conference is scheduled for May 17, 2005. Trial is scheduled to begin June 1, 2005.

FACTUAL BACKGROUND

REDACTED

REDACTED

REDACTED

REDACTED

ARGUMENT

REDACTED

Pursuant to Rule 408, statements made in the context of compromise negotiations are not admissible as proof of liability for, or invalidity of, a disputed claim. Rule 408 states in relevant part:

> "Evidence of (1) furnishing or offering or promising to furnish, or (2) accepting or offering or promising to accept, a valuable consideration in compromising or attempting to compromise a claim which was disputed as to either validity or amount, is not admissible to provide liability for or invalidity of the claim or its amount. Evidence of conduct or statements made in compromise negotiations is likewise not admissible."

See also Pharmastem Therapeutics, Inc. v. Viacell Inc., 2003 WL 22387038 at *3-4 (D. Del.) (granting motion in limine excluding evidence of settlement negotiations between adverse parties on grounds that such evidence is "plainly inadmissible under Rule 408.") "The purpose of Rule 408 is 'to encourage full and frank disclosure between parties in order to promote settlements, rather than protracted litigation.' " Id. at *4.

REDACTED

CONCLUSION

For the reasons set forth above, DOT respectfully requests that DOT's motion in limine to preclude evidence or argument relating to compromise negotiations concerning the bone filler patents, as well as evidence or argument regarding the timing of DOT's assertion of detailed non-infringement and invalidity contentions regarding the bone filler patents.

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Original Filing Date: May 10, 2005

Redacted Filing Date: May 20, 2005

EXHIBIT 1

Confidential Exhibit –
Redacted

EXHIBIT 2

Confidential Exhibit –
Redacted

EXHIBIT 3

Confidential Exhibit –
Redacted

EXHIBIT 4

Confidential Exhibit –
Redacted

EXHIBIT 5

Confidential Exhibit –
Redacted

EXHIBIT 6

Westlaw.
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2003 WL 22387038 (D.Del.)
(Cite as: 2003 WL 22387038 (D.Del.))

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Motions, Pleadings and Filings

Only the Westlaw citation is currently available.

United States District Court,
D. Delaware.
PHARMASTEM THERAPEUTICS, INC., Plaintiff,
v.
VIACELL INC., Cryo-Cell International, Inc., Corcell, Inc., Stemcyte, Inc., Cbr Systems, Inc. f/k/a Cord Blood Registry, Inc., Birthcells Technology, Inc., Nustem Technologies, Inc., and Bio-Cell, Inc., Defendants.
No. C.A. 02-148 GMS.

Oct. 7, 2003.

Philip A. Rovner, Potter Anderson & Corroon, LLP, Wilmington, DE, for Plaintiff.

Jeffrey L. Moyer, David Allan Felice, Richards, Layton & Finger, Robert F. Stewart, Jr., Dilworth, Paxson LLP, Richard D. Kirk, Morris, James, Hitchens & Williams, Wilmington, DE, for Defendants.

MEMORANDUM AND ORDER

SLEET, J.

I. INTRODUCTION

***1** On August 5, 2003, PharmaStem Therapeutics, Inc. ("PharmaStem") filed a motion *in limine* to exclude from evidence all discovery relating to settlement negotiations regarding patent licensing agreements. On August 12, 2003, Viacell Inc., Cryo-Cell International, Inc., Corcell, Inc., Stemcyte, Inc., CBR Systems, Inc. f/k/a Cord Blood Registry, Inc., Birthcells Technology, Inc., Nustem Technologies, Inc., and Bio-Cell, Inc. (collectively "Viacell") filed an answer requesting that PharmaStem's motion be denied. Alternatively, Viacell moved to exclude from evidence the license agreements between PharmaStem and third parties, Anthrogenesis Corporation ("Anthrogenesis") and Stembanc, Inc. ("Stembanc"), and to preclude PharmaStem's expert, Russell Parr, from relying on those licenses as a factor in determining a reasonable royalty rate. On August 15, 2003, PharmaStem filed a reply. The court conducted a pretrial conference on September 8, 2003 in which it heard oral argument from the parties on PharmaStem's motion. Upon consideration of the arguments raised at the pretrial conference and in the parties' briefs, the court will grant PharmaStem's motion *in limine* to exclude from evidence all discovery relating to settlement negotiations regarding the Anthrogenesis and Stembanc licenses and with any of the defendants in this case. The court will also grant Viacell's cross-motion *in limine* to exclude from evidence the Anthrogenesis and Stembanc license agreements themselves and to preclude Mr. Parr from relying on those licenses as a factor in determining a reasonable royalty rate. The court bases its ruling on the following reasons.

II. DISCUSSION

After the commencement of the present litigation, PharmaStem licensed the patents-in-suit to two, non-defendant companies, Anthrogenesis and Stembanc. PharmaStem entered into licensing agreements with Anthrogenesis and Stembanc in the context of settling a claim of infringement against each of those companies. PharmaStem also has held settlement negotiations with several of the defendants. In all instances, PharmaStem and the various parties entered into a negotiation agreement containing the following clause:

> All offers, promises, conduct and statements, whether oral or written made in the course of negotiations relating to the Patents by either of the parties, their attorneys, agents or representatives are "Confidential Statements." Confidential Statements may not be disclosed by the receiving party without the consent of the disclosing party. Confidential Statements are subject to Rule 408 of the Federal Rules of Evidence may not be used by the receiving party in litigation for any purpose including, without limitation, impeachment. However, evidence that is otherwise admissible or discoverable shall not be rendered inadmissible or non-discoverable as a result of its presentation or use in connection with this Agreement.

PharmaStem claims that evidence related to the negotiations underlying the Anthrogenesis and Stembanc license agreements is inadmissible under

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Rule 408 of the Federal Rules of Evidence. PharmaStem maintains, however, that the Anthrogenesis and Stembanc license agreements themselves are admissible to establish the appropriate reasonable royalty calculation. Accordingly, PharmaStem's damages expert, Russell Parr, relied on the license agreements in reaching his opinion that PharmaStem is entitled to a high royalty rate for the patents-in-suit.

***2** Conversely, Viacell takes an "all-or-nothing" position, arguing that if the underlying negotiations are inadmissible because of Rule 408, then the license agreements themselves are also inadmissible for the same reason. If Mr. Parr is nonetheless permitted to rely on the Anthrogenesis and Stembanc licenses, Viacell argues that it then should be permitted to introduce the underlying negotiations to show that the final agreements were not the product of a freely negotiated, bargained-for exchange. Indeed, Viacell's damages expert, David E. Yurkerwich, relied on evidence of the underlying negotiations to reach his conclusion that the reasonable royalty rate should be much lower than the one Mr. Parr calculated. The court agrees that PharmaStem is not permitted to have it both ways.

"[T]he methodology for determining a 'reasonable royalty' is consigned to the district court's discretion and is reviewed only for abuse of that discretion." *Century Wrecker Corp. v. E.R. Buske Mfg. Co., Inc.*, 898 F.Supp. 1334, 1336 (N.D.Iowa 1995) (citing *Wang Labs., Inc. v. Toshiba Corp.*, 993 F.2d 858, 869 (Fed.Cir.1993); *SmithKline Diagnostics, Inc. v. Helena Labs. Corp.*, 926 F.2d 1161, 1164 (Fed.Cir.1991); *Fromson v. Western Litho Plate & Supply Co.*, 853 F.2d 1568, 1576 (Fed.Cir.1988)). It is well established that a patent holder's license agreements with third parties are permissible considerations in a reasonable royalty calculation. *See, e.g., Georgia-Pacific Corp. v. U.S. Plywood Corp.*, 318 F.Supp. 1116, 1120 (S.D.N.Y.1970). However, notwithstanding their relevance to a reasonable royalty calculation, the court may exclude license agreements between a patent holder and third parties under Rule 408 of the Federal Rules of Evidence.

Rule 408 states in pertinent part:

> Evidence of (1) furnishing or offering or promising to furnish, (2) accepting or offering or promising to accept, a valuable consideration in compromising or attempting to compromise a claim which was disputed as to either validity or amount, is not admissible to prove liability for or invalidity of the claim or its amount. Evidence of conduct or statements made in compromising negotiations is likewise not admissible.

Fed.R.Evid. 408. Specifically, a license agreement may be excluded from evidence under Rule 408 where it (1) was reached under a threat of litigation, (2) arose in a situation where litigation was threatened or probable, or (3) was negotiated against a backdrop of continuing litigation infringement. *See Century Wrecker*, 898 F.Supp. at 1340 (citing *Studiengesellschaft Kohle, M.b.H. v. Dart Indus., Inc.*, 862 F.2d 1564, 1572 (Fed.Cir.1988) (synthesizing the teachings of *Panduit Corp. v. Stahlin Bros. Fibre Works, Inc.*, 575 F.2d 1152, 1164 n. 11 (6th Cir.1978), *Rude v. Westcott*, 130 U.S. 152, 164, 9 S.Ct. 463, 32 L.Ed. 888 (1889), *Hanson v. Alpine Valley Ski Area, Inc.*, 718 F.2d 1075, 1078-79 (Fed.Cir.1983), and *Deere & Co. v. Int'l Harvester Co.*, 710 F.2d 1551, 1557 (Fed.Cir.1983), respectively)). The court must look carefully at the context in which the license agreement was reached to determine whether it meets any of these requirements. *See Dart Indus.*, 862 F.2d at 1572; *Century Wrecker*, 898 F.Supp. at 1340.

***3** The license agreements between PharmaStem and third parties Anthrogenesis and Stembanc arose in a context where litigation was threatened or at least probable. PharmaStem in fact states, "With respect to Anthrogenesis and Stembanc, discovery obtained unambiguously refers to the amounts contemplated to settle PharmaStem's claim of infringement against them." (PharmaStem Therapeutics, Inc's Motion *In Limine* to Exclude All Discovery Relating to Settlement Agreement Negotiations Regarding Patent License Agreements, at 3). Additionally, PharmaStem's negotiation agreements with Anthrogenesis and Stembanc specifically reference Rule 408, indicating that the parties involved must consider the licenses to have arisen out of settlement negotiations over the validity or amount of an infringement claim. A "dispute" under Rule 408 includes "both litigation and less formal states of a dispute." In view of the term's broad construction, it is clear that the Anthrogenesis and Stembanc license agreements arose from a dispute within the meaning of Rule 408.

Both PharmaStem and Viacell cite *Century Wrecker* in support of their respective positions. In *Century Wrecker*, the court admitted evidence of license agreements between the plaintiff and third parties, which arose out of the threat of litigation. Although the court noted that the agreements were inadmissible under Rule 408, it nonetheless allowed the

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defendants to introduce the agreements into evidence because the plaintiff's expert had relied on them in his reasonable royalty calculations. The court reasoned that the defendants were entitled to use the settlement agreements to challenge the basis of the plaintiff's expert's conclusions.

Century Wrecker, however, is not binding precedent on this court. Moreover, *Century Wrecker* held only that the actual settlement agreements were admissible to challenge the basis of the expert's opinion. The case, therefore, does not dictate Viacell's position that evidence of negotiations *underlying* the license agreements must be admitted to challenge Mr. Parr's report. Nor does *Century Wrecker* mandate PharmaStem's conclusion that the Anthrogenesis and Stembanc licenses are automatically admissible because Mr. Parr used them to calculate a reasonable royalty.

The court is not required to allow otherwise inadmissible settlement agreements into evidence simply because one party's expert relies on them in reaching a reasonable royalty. This is particularly true where other options, such as excluding the licenses altogether, are available to the court. The purpose of Rule 408 is "to encourage full and frank disclosure between parties in order to promote settlements, rather than protracted litigation." *See* Fed.R.Evid. 408 (citing *Olin Corp. v. Ins. Co. of N. Am.*, 603 F.Supp. 445, 449 (S.D.N.Y.1985)). Given its discretion to determine the methodology for calculating a reasonable royalty, the court finds that it is the better practice to exclude the Anthrogenesis and Stembanc licenses in view of the policy considerations behind Rule 408. *See Bradbury v. Phillips Petroleum Co.*, 815 F.2d 1356, 1364 (10th Cir.1987) ("[W]hen the issue is doubtful, the better practice is to exclude evidence of compromises or compromise offers.").

***4** Finally, although Viacell does not appear to seek the introduction of such evidence, to the extent PharmaStem requests the exclusion of settlement negotiations between itself and any of the defendants in this case, that evidence is plainly inadmissible under Rule 408. *See* Fed.R.Evid. 408 ("Evidence of conduct or statements made in compromising negotiations is likewise not admissible.").

III. CONCLUSION

Because the agreements arose in a context where litigation was threatened or at least probable, the court will exclude all evidence relating to negotiations of the Anthrogenesis and Stembanc licenses, including the license agreements themselves.

Therefore, IT IS HEREBY ORDERED that:

1. PharmaStem Therapeutics, Inc.'s motion *in limine* to exclude from evidence all discovery relating to settlement negotiations regarding the Anthrogenesis and Stembanc licenses and with any of the defendants in this case is GRANTED.
2. Viacell's cross-motion *in limine* to exclude from evidence the Anthrogenesis and Stembanc license agreements and to preclude Russell Parr from relying on those licenses as a factor in determining a reasonable royalty rate is GRANTED.
3. The parties' experts may not rely on the Anthrogenesis and Stembanc licenses or any documents or other evidence pertaining to negotiations of the those licenses to calculate a reasonable royalty rate or to challenge the opposing party's calculation of a reasonable royalty rate.

2003 WL 22387038 (D.Del.)

Motions, Pleadings and Filings **(Back to top)**

• 2003 WL 23310808 (Verdict and Settlement Summary) (Oct. 29, 2003)

END OF DOCUMENT

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CERTIFICATE OF SERVICE

I, Maryellen Noreika, hereby certify that copies of the foregoing were caused to be served this 20th day of May, 2005 upon the following in the manner indicated:

BY HAND DELIVERY

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/s/ Maryellen Noreika (#3208)
Maryellen Noreika (#3208)

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. No. 04-204-JJF **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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EXHIBIT 1

In The Matter Of:

Kyphon, Inc. v.
Disc-O-Tech Medical Technologies Ltd., et al.

Hearing
April 19, 2005

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE
KYPHON, INC.,)
Plaintiff,)
v.) C.A. No. 04-204-JJF
DISC-O-TECH MEDICAL)
TECHNOLOGIES, LTD.,)
And DISC ORTHOPAEDIC)
TECHNOLOGIES, INC.,)
Defendants.)
Tuesday, April 19, 2005
1:03 p.m.
Courtroom 2B
844 King Street
Wilmington, Delaware
BEFORE: THE HONORABLE VINCENT POPPITI
United States District Court Judge
DALE R. DUBE, ESQ.
BLANK ROME, LLP
APPEARANCES:
THOMAS HALKOWSKI, ESQ.
FRANK SCHERKENBACH, ESQ.
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Page 2

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THE COURT: I'm sorry that I was with Judge Farnan longer that we both expected. Please don't stand. Sit.

So we'll need just a few minutes, so if you'll all make yourselves comfortable, please.

Before we begin and this can be off the record.

(Following a discussion held off the record:)

THE COURT: Your current pretrial, I believe, is scheduled for May 24th at 3:00 p.m.

MR. HALKOWSKI: That's correct, Your Honor.

THE COURT: Judge Farnan, as a result of some other commitments, would like to move that pretrial to the week of May the 16th. And he advises me that any time on either Tuesday the 17th or Wednesday the 18th would be good for his calender.

We don't need to do that now, but I would like to advise him by the close of what we're doing today as to what date and time would be good for all of you.

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The other is also really I expect just a matter of housekeeping. For purposes of housekeeping the docket entries, I don't have a docket number. But in defendant Disc-O-Tech's motion for summary judgment of non-infringement of patents '888, '404 and '043(b)1 at Page 2.

Do you have that, please? Thank you. It is dated April 6th.

MR. SOBEL: Yes, Your Honor.

THE COURT: I would expect you would want to consider filing a substitute page. And I think if you look at the language at Paragraphs 2, 3, 4 and 5, where there should be a word not inserted. Unless that's a major concession, then we can all go home.

MR. HALKOWSKI: I was going to say if that's not the case, we've got to add on another 30 minutes.

MR. LOBENFELD: I was waiting for them to say so stipulated.

THE COURT: I thought it was important for purposes of —

MR. LOBENFELD: I appreciate it.

THE COURT: You know when you have

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so much paper, and now I'm on the — still on the receiving end of looking at this, not generating it, and I say this respectfully, it happens. But I want your papers to be as they should be for view by anyone else other than me at this point.

MR. LOBENFELD: Thank you, Your Honor.

MR. SOBEL: Thank you, Your Honor.

THE COURT: And with that, let's proceed to the business of the day, please.

MR. SCHERKENBACH: Thank you, Your Honor. I'd like to hand up — the first thing I'd like to do is introduce another colleague with me, Ms. Rama Elluru, from the D.C. office.

THE COURT: And your name again?

MS. ELLURU: Rama Elluru.

MR. SCHERKENBACH: She will be assisting us, and also David Shaw, vice president and general counsel.

THE COURT: Mr. Shaw, good afternoon.

MR. SCHERKENBACH: If I may, Your Honor, I'd like to hand up copies of presentations so you don't have to worry about

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sort of getting everything down, just make notes on it. I've provided counsel with a copy.

THE COURT: And if you'll excuse me while I open a package of highlighters.

MR. SCHERKENBACH: Okay.

THE COURT: I really — this microphone is intimidating.

MR. SCHERKENBACH: I usually just push it aside. This courtroom is small enough.

THE COURT: I'm going to do that.

MR. SCHERKENBACH: You don't need it.

THE COURT: I don't need it, that's true. Okay. Please.

MR. SCHERKENBACH: Okay. We have prepared our presentation in three modules to track the motions: claim construction, infringement, and validity.

And I thought it would be useful, because there are some issues with some schematic issues that cut across those modules to sort of — sort of step through it in order.

The goal here, of course, is to help your understanding. So whatever helps you,

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please. Questions during the presentation probably are better than at the end of it, if you find that helpful.

If you — one other thing I guess I should tell you is attached to the copy I gave you, Your Honor, are a few — I know you've been dying to receive them — a few more dictionary definitions. These are from the same sources that Disc-O-Tech cited in their opposition on the grounds claim construction paper.

We thought it would be helpful to have everything in context. I'm going to refer to some of these in the presentation, so you have them there.

THE COURT: Thank you.

MR. SCHERKENBACH: Okay. Go ahead. So, first of all, an overview of what we're going to cover. As I say, a claim construction, infringement, and validity. There has been an avalanche of paper in the case, but I think actually boiled down, the issues are quite simple.

On claim construction the issue, overarching issue for all the patents and really

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all the terms is: Should the claims be limited to what's disclosed in the specification or not?

When the plain and ordinary meaning of the claim language is broad enough, should we limit the claim language to the specification?

Should we — there's a well developed body of law on that. One of the things I'm going to do is try to make a little bit of sense of that for you. And if we apply that principle,

a piece of wood or piece of sheet [5] rock at home, you go through. When you drill, [6] you drill into the — you drill into — you drill [7] into the space to create a hole through [8] something.

[9] When you're drilling to fenestrate, [10] you're creating a hole. You are creating a [11] passage.

[12] You are creating a channel. Now, [13] what is happening when you create a channel, you [14] are increasing the volume of that passage.

[15] So the passage goes to here with a [16] drill. And then all this is increasing the [17] volume of the passage.

[18] You don't want to consider all this [19] area, which has the arrows as the — increasing [20] the volume passage. Certainly there's increase [21] in the volume passage from here to here.

[22] That's the whole point of the [23] Edeland. That's the whole nature of what Kyphon [24] is telling the FDA, conventional bone tamps. Do

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[1] they go in? They compact by increasing the [2] volume of the passage.

[3] We — Kyphon are only different [4] because we inflate. Also, in Edeland, you're not [5] pushing just once, pushing a number of times. So [6] each of those pushes, each of those independent [7] pushes is increased, further increasing the [8] volume of that passage.

[9] **MR. LOBENFELD:** Jonathan, go back [10] and read that.

[11] **THE COURT:** You want the language [12] read in?

[13] **MR. SOBEL:** This is from Edeland [14] Exhibit A-17 at Page 687. "The compressed [15] fracture region is reduced by repeated careful [16] pushes of the probe. Figure 3.

[17] On the way, the probe transfers and [18] compacts considerable amounts of cancellous bone [19] from the region beneath the depression, filling [20] the passage. Tricalcium phosphate.

[21] At the end of the day, tricalcium [22] phosphate at the time of Edeland was a slurry. [23] We had the dispute.

[24] Dr. Marks disputes how fast it could

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[1] set to harden. We cited Brown and Shout. [2] Admittedly, they're dated after the Olerud [3] article.

[4] Those were partially in this [5] tricalcium phosphate slurry that's set to a [6] hardened condition.

[7] Kyphon can't have it both ways by [8] writing in that kind of limitation, time [9] limitation into setting to a hardened condition.

[10] Bone fillers, as they said in [11] Section 6 of their 510(k), were around since the [12] 1960s. By the way, it's not in the record, [13] Plaster of Paris that he said could be put in the [14] void was around since the 1940s.

[15] And he said that could set to a [16] hardened condition. It could.

[17] Kennedy, methyl methacrylate, the [18] same type — the Edeland — it's in our papers at [19] Exhibit A-18, same type of fracture reduction [20] using methyl methacrylate, same type, much like a [21] bunch of the several other references that we [22] claim anticipate the patent. We focus on our [23] patent in Olerud and Edeland.

[24] **THE COURT:** Go back to the last

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[1] slide, will you please?

[2] **MR. SOBEL:** This is Kennedy.

[3] **THE COURT:** Right.

[4] **MR. SOBEL:** Okay. Reducing the [5] fracture creating a void, reducing the fracture [6] just like Edeland. He wants capable of setting [7] to a hardened condition. It's in.

[8] It's in your hands. I don't even [9] think, frankly, they — Mr. Scherkenbach, in his [10] rebuttal, can correct me if I'm wrong. They've [11] agreed there's compaction.

[12] They're compacting cancellous bone [13] with both of these references. They're down to [14] arguing whether you're increasing the volume of a [15] passage.

[16] Again, Dr. Mitchell or not again, [17] but Dr. Mitchell did the Edeland procedure. He [18] filled it with a flowable material, methyl [19] methacrylate.

[20] Edeland, when you're compacting, [21] this is the central portion of the bone. Okay.

[22] It's compacting away from the [23] central portion of the bone. Like Olerud, it, [24] too, is compacting away from the center.

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[1] And then drilling — I don't know [2] whether they contest this to any degree or great [3] degree. You are fenestrating.

[4] As Mr. Scherkenbach said, you [5] fenestrate with a drill, and you are doing it [6] under x-ray control. That's not disputed. It's [7] disclosed in Edeland.

[8] Fenestration under fluoroscopic or [9] x-ray control. These are statements from Kyphon [10] on Slide 45 about how — about drilling the '888. [11] Osteoporotic bone is just broken down, soft deep [12] osteoporotic, broken down weak interior bone.

[13] Okay. If you — in Olerud, if [14] you're in there compacting cancellous bone and [15] it's strong bone, you know, if you can compact [16] strong bone, you can compact weak bone.

[17] It doesn't matter what's in there. [18] Edeland discloses osteoporotic bone. Olerud [19] doesn't have osteoporotic bone.

[20] Our point is bone, cancellous bone [21] if you — if you're disclosing compacting hard [22] strong inner bone, then inherent subsumed by that [23] is weakened inner bone.

[24] Obviousness, in 60 seconds' time.

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[1] What we are pointing out here is if this thing is [2] going to come down to whether you had a flowable [3] material capable of setting to a hardened [4] condition, we are focusing in on the 1989 filing [5] date. What does the prior art show?

[6] Kennedy is showing methyl [7] methacrylate in the same procedure. No dispute, [8] methyl methacrylate is a flowable material [9] capable of setting to a hardened condition.

[10] Today it's put in a paste form. [11] Brown and Chow, later than Edeland, show calcium [12] phosphate hardening into cement.

[13] Same procedure. You are charged [14] with knowing of a reference in the same field.

[15] This is a case that Dance — the [16] Dance case 160 F.3d 1339 in Kyphon's papers, [17] this notion about how long it took someone to [18] find a reference. You're charged with knowing [19] the reference.

[20] Quickly, on secondary [21] considerations, the praise for the device is a [22] balloon. You're going to put what in there, a [23] thumb-shaped balloon? Wow.

[24] This balloon works so great. This

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[1] balloon is wonderful. What a miraculous balloon.

[2] We don't contest that the balloon is [3] novel. But if it's not limited to a balloon, [4] there's no secondary consideration to speak of. [5] And it is not limited if the claims do not [6] require a balloon. They're anticipated and [7] rendered obvious by the prior art.

[8] Thank you.

[9] **THE COURT:** Thank you.

[10] **MR. LOBENFELD:** Your Honor, we're [11] going to rest on our papers on the bone filler [12] patents given the shortness of time.

[13] **THE COURT:** Okay. Just one moment, [14] please.

[15] Proceed, please.

[16] **MR. SCHERKENBACH:** No break?

[17] **THE COURT:** Well, do you want to [18] take a break?

EXHIBIT 2

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. No. 04-204-JJF

KYPHON'S OPPOSITION TO DEFENDANTS' MOTION FOR SUMMARY JUDGMENT THAT THE '404 AND '888 PATENTS ARE INVALID BASED ON ANTICIPATION AND/OR OBVIOUSNESS

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DATED: April 14, 2005

> teaching, or motivation in the prior art, arising from what the prior art would have taught a person of ordinary skill in the field of the invention.

In short, because DOT fails to provide any such meaningful suggestion to combine, DOT's request for a summary judgment that the asserted patent claims would have been obvious fails for this reason alone.

B. DOT fails to address the "objective factors" of nonobviousness, which must be considered by the court

The final factors that must be considered in an obviousness analysis are the so-called "objective factors" or "secondary considerations." These objective factors, which serve "as insurance against the insidious attraction of the siren hindsight," *W.L. Gore*, 721 F.2d at 1553, include commercial success, long felt but unresolved need, initial skepticism, and praise. *Panduit*, 810 F.2d at 1569; *see also Graham*, 383 U.S. at 17-18. The reasoning is straight-forward: if an invention had 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 earlier. These objective factors ***must*** be considered in any obviousness analysis. "[T]he judicial process requires that a court withhold a conclusion of obviousness until it has fully assessed the impact of any objective evidence of nonobviousness. Only then can a court base its judgment, as it must, on all probative evidence of record." *Panduit*, 810 F.2d at 1570-71 (emphasis omitted) (citing *Simmons Fastener Corp. v. Illinois Tool Works, Inc.*, 739 F.2d 1573 (Fed. Cir. 1984) and *Stratoflex Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983) (holding that "evidence rising out of the so-called 'secondary considerations' must always when present be considered en route to a determination of obviousness")).

Despite the requirement that the objective factors be considered, DOT's motion is silent on them. For this reason as well, DOT's motion for summary judgment of obviousness must fail.

For instance, there is no dispute that Kyphon's kyphoplasty line is commercially successful. DOT even emphasized this success in its opposition to Kyphon's preliminary injunction:

> Plaintiff is a very large, successful medical device company that manufactures surgical devices utilizing balloon technology to repair spinal fractures. Plaintiff has hundreds of employees, over $131million in net sales last year [2003], and commands ***99.7%*** of the market for the devices at issue. Plaintiff's net sales in the first nine months of 2004 were $151million, a 65% increase over the same period in 2003. Plaintiff estimates that its revenues from sales in 2004 will be between $210 and $213 million. As of December 31, 2003, over 60,000 spine surgeries had been performed using Plaintiff's instruments.

[D.I. 83 at 3. Citations and footnote omitted. Emphasis in original.]

DOT does not dispute that Kyphon's product embodies the claimed invention. Indeed, DOT emphasizes that fact in its motion. Where the product embodies the claimed invention, courts presume that the commercial success is due to the invention. *Echolochem v. Southern California Edison*, 227 F.3d 1361, 1377 (Fed. Cir. 2000). DOT does not even attempt to rebut this nexus.

This undisputed showing of commercial success precludes the grant of summary judgment of obviousness. *Pro-Mold and Tool Co., Inc. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568 (Fed. Cir. 1996) (vacating grant of summary judgment because the patentee's evidence of commercial success raised a genuine issue of material fact).

There is also evidence of long felt, but unresolved need, initial skepticism, and praise. For instance, a recent article in Forbes reported:

> 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.

The Inflatable Spine, FORBES, June 7, 2004, at 227 [D.I. 146 Ex. C]; *see also Kyphoplasty Employs Bone Balloon to Correct Kyphosis Due to Fractures*, ORTHOPEDICS TODAY, Nov. 1999 (KY230109-10) [D.I. 146 Ex. D] (quoting one physician as stating, "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" and noting that the last patient treated by the physician "arrived in a wheelchair due to back pain and walked out to go home 1 1/2 hours later").

These are but two bits of the wealth of evidence that goes to the nonobviousness of the '888 and '404 patents, yet DOT completely ignores this evidence and the analysis that is required in any obviousness determination. Its motion must therefore, be denied.

VII. CONCLUSION

As Dr. Marks's expert report and the other evidence in this case demonstrates, there are numerous genuine issues of material fact connected with both the Olerud and Edeland references. Kyphon therefore respectfully requests that the Court deny DOT's motion for summary judgment relating to invalidity and let this decision be made by the fact-finder in the best position to make it: the Jury.

CERTIFICATE OF SERVICE

I, Maryellen Noreika, hereby certify that copies of the foregoing were caused to be served this 10th day of May, 2005 upon the following in the manner indicated:

BY HAND DELIVERY

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