# EXHIBIT 1

**In The Matter Of:**

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

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*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.
RAMA ELLURU, ESQ.
FISH & RICHARDSON
-and-
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KYPHON
Counsel for the Plaintiff

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APPEARANCES CONTINUED:
MARYELLEN NOREIKA, ESQ.
MORRIS, NICHOLS, ARSHT & TUNNELL
-and-
ERIC J. LOBENFELD, ESQ.
JONATHAN M. SOBEL, ESQ.
ARLENE L. CHOW, ESQ.
ROBERT J. DeMENTO, ESQ.
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Counsel for the Defendants

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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.,<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 |

**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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KYPHON, INC.

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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