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

DEFENDANTS DISC-O-TECH MEDICAL TECHNOLOGIES, LTD.'S AND DISC ORTHOPAEDIC TECHNOLOGIES, INC.'S MOTION FOR JUDGMENT AS A MATTER OF LAW OF NONINFRINGEMENT OF THE '043 PATENT

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NATURE AND STAGE OF THE PROCEEDINGS

On June 20 and June 21, 2005, a jury trial was held on the issue of whether defendants, Disc-O-Tech Medical Technologies, Ltd. and Disc Orthopaedic Technologies Inc. (collectively "DOT"), infringe claim 17 of Kyphon's U.S. Patent No. 6,235,043 ("the '043 Patent").

DOT hereby moves for judgment as a matter of law against Kyphon Inc. ("Kyphon") on the issue of noninfringement of the '043 Patent.[1]

[1] DOT does not waive any of its previously-made claim construction arguments that have been rejected by the Court and expressly reserves such arguments for appeal.

ARGUMENT

Under Rule 50(a) of the Federal Rules of Civil Procedure , the Court is empowered during a trial to rule against a party on an issue if "there is no legally sufficient evidentiary basis for a reasonable jury to find for that party on that issue."[2] "The question is not whether there is literally no evidence supporting the party against whom the motion is directed but whether there is evidence upon which the jury could properly find for that party." Walter v. Holiday Inns, Inc., 985 F.2d 1232, 1238 (3d Cir. 1993) (citation omitted); *see* Lifescan, Inc. v. Home Diagnostics, Inc., 103 F. Supp. 2d 345, 351 (D. Del. 2000), aff'd, No. 00-1485, 00-1486, 2001 WL 345439 (Fed. Cir. Apr. 06, 2001) (unpublished – not cited for precedent). Here, no reasonable jury could conclude that DOT infringes the '043 Patent.

DOT IS ENTITLED TO JUDGMENT AS A MATTER OF LAW THAT IT DOES NOT INFRINGE THE '043 PATENT.

A. DOT's SKy Device Does Not Meet All Of The Limitations Of Claim 17.

For an accused method to literally infringe a claim, the accused method must contain exactly each and every limitation of the invention as defined by the patent claim. Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co., 520 U.S. 17, 29 (1997). If the accused method omits even a single limitation recited in a patent claim, it does not literally infringe that claim.

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[2] In lieu of a statement of facts, the pertinent facts are incorporated in the Argument section.

Here, Kyphon argues that because the SKy device expands to a "predetermined configuration," it infringes. As Kyphon's Dr. Marks conceded, however, the words "predetermined configuration" are not in the claims (Trial Tr. at 292). Indeed, Claim 17 states ('043 Patent at Claim 17):

> A method for treating bone comprising the steps of
>
> inserting inside a bone a device comprising a body adapted to be inserted into bone and undergo expansion in cancellous bone to compact cancellous bone, the body including at least two materials that, during the expansion in cancellous bone, apply a force capable of moving fractured cortical bone and constrain the expansion in cancellous bone,
>
> causing constrained expansion of the body in cancellous bone, and
>
> compacting cancellous bone by the constrained expansion.

On its face, claim 17 clearly requires that the expandable body adapted to be inserted into bone must be comprised of two materials.[3] Kyphon's expert, Dr. Marks, agreed (Trial Tr. at 294-96):

> Q. So it wasn't whether the device has two materials, it's whether the expandable body has two materials; right, Dr. Marks?
>
> A. It says the body including at least two materials.
>
> Q. Okay. Right. Not the device as a whole, the expandable body; right?
>
> A. Correct.
>
> * * *

[3] The Special Master's Opinion and Order on Claim Construction adopted the plain and ordinary meaning of the claim terms of claim 17. (See D.I. 212 at 17-18.)

> Q. The claim is talking about **a body that's expandable, but which has two materials** which constrain the expansion. Isn't that what the claim is talking about?
>
> A. That's exactly what the claim says.

Similarly, the inventor of the '043 patent, Dr. Reiley, testified (Trial Tr. at 162-163).

> Q. You see that Claim 17 requires that a device that has a body?
>
> A. Yes.
>
> * * *
>
> Q. The body undergoes expansion?
>
> A. That's correct.
>
> Q. And the body that undergoes expansion includes at least two materials?
>
> A. That's correct.
>
> Q. The body that undergoes expansion includes two materials that constrain expansion in the inner bone; correct?
>
> A. That's correct.

As Kyphon's Dr. Marks testified, however, the expandable body of the accused SKy Bone Expander Device (the "SKy Device") is the polymer tube alone (Trial Tr. at 195):

> Q. And I think you testified at your deposition that the polymer tube is the expandable body; right?
>
> A. That's the part that's expanding.
>
> Q. Okay. So, and we agree the polymer tube is the expandable body?

A. That's correct.

This was confirmed by DOT's witnesses who testified that the expandable body of the SKy Device is the polymer tube (e.g., Trial Tr. at 323-24), which is a single material. The SKy Bone device does not have an expandable body including a second material and thus cannot infringe claim 17.

Moreover, claim 17 requires that the expandable body "including at least two materials … constrain the expansion in cancellous bone." The SKy Bone device does not have a second material period, let alone one that constrains expansion of the tube. As Drs. Mitchell and Beyar testified, the size and shape of the SKy Device in its expanded form is determined solely by the size and configuration of the slits in the polymer tube (Tr. 324, 327-28, 401). Therefore no reasonable jury could find that the SKy device infringes claim 17.

B. The "End Cap" Of The SKy Device Is Not A Second Material That Constrains Expansion Of The Expandable Body.

Kyphon argues that the end cap/inner rod is the second material that constrains the expansion of the expandable body. But Kyphon's argument is flawed, because Kyphon's own expert admitted that "the end cap permits [the polymer tube] to expand" (Trial Tr. at 305). Without the end cap, the SKy Device would not expand at all (Trial Tr. at 295, 305, 327-28).[4] It would simply be a broken device. The end cap does not restrict the expansion of the polymer tube (Trial Tr. at 327). To the contrary, it

[4] So too, the inner rod does not determine what the shape of the expanded device will be (Trial Tr. at 326-27). The inner rod facilitates the expansion and allows the device to work (*id*). In other words, without the inner rod, there is no expansion to constrain.

actually enables the expansion of the body – the exact opposite of constraining expansion of the body. The end cap thus does not constrain expansion.

C. The "Over Tube" Or Sheath Is Not A Second Material That Constrains Expansion Of The Expandable Body.

Kyphon has suggested that the over tube or sheath of the SKy Bone device is the second material that constrains expansion in the SKy Bone device. Notably, this is an argument that Dr. Marks, Kyphon's expert, did not make. And Kyphon did not present any witnesses who testified that the overtube constrained expansion.

Kyphon attempted to extract testimony from DOT's witnesses regarding the over tube, but there simply is no support for Kyphon's argument. As Dr. Beyar, one of the developers of the SKy device, with or without the overtube the SKy device will expand to the same configuration (Trial Tr. at 351). Thus, the overtube does not constrain expansion. There is no testimony to the contrary. Indeed, the evidence at trial showed that the overtube simply controls the timing and sequence of expansion (Trial Tr. at 355). It has no effect on the shape of the device. (Trial Tr. at 346).

CONCLUSION

For the foregoing reasons, DOT respectfully requests that the Court enter Judgment as a Matter of Law for noninfringement of the '043 Patent for on the grounds set forth herein.

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June 21, 2005

CERTIFICATE OF SERVICE

I, Maryellen Noreika, hereby certify that on June 22, 2005 I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing(s) to the following:

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