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 DOT'S UNTIMELY MOTION *IN LIMINE* TO PRECLUDE TESTIMONY FROM DR. HALLIDAY REGARDING OBJECTIVE INDICIA OF NON-OBVIOUSNESS

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DATED: June 14, 2005

DOT's motion to preclude a witness from a significantly pared-back Kyphon witness list is both untimely and without merit. DOT's real complaint is that it has finally realized that it will only have party employees and paid experts at trial to testify on its behalf, while Kyphon had a wealth of third-party witnesses from which it has chosen Dr. Halliday. However, this is not the sort of "prejudice" that the Federal Rules of Evidence are designed to prevent. No amount of spin by DOT will change the fact that Dr. Halliday is a lay witness, and that Kyphon is entitled to present her testimony regarding objective indicia of non-obviousness.

Dr. Halliday's status as an orthopedic surgeon does not mean that any testimony she provides automatically becomes expert testimony. Contrary to DOT's implication, Dr. Halliday will not be comparing either the accused product or the asserted prior art to the claim language; nor need she do so. Her testimony regarding objective indicia of non-obviousness will instead be based on her personal knowledge and perceptions – e.g., her experiences before and after the invention of kyphoplasty, including her general approach for previously treating her patients versus how she now treats her patients; what she has seen and experienced with regard to the obvious physical conditions of her patients with and without the treatment of kyphoplasty; and her own experiences regarding use of Kyphon's device. Such testimony concerns basic information based upon first-hand knowledge that is not expert opinion testimony within the meaning of Rule 702.

1. Dr. Halliday Will Not Provide Expert Testimony Under FRE 702

DOT's entire analysis is based on the assumption that any testimony regarding secondary considerations must be expert testimony. DOT's assumption is faulty, as it

ignores the approach of: (i) presenting lay witnesses to provide factual information regarding various objective indicia of non-obviousness (e.g., unfavorable experiences before invention was developed versus positive experience after the invention was put to use; and success of the invention); and (ii) expert testimony that establishes a nexus between the facts and the invention by opining that the commercial embodiments fall within the asserted patent claims. Indeed, as the Court undoubtedly is aware, this combination of lay testimony provided by fact witnesses, followed by an expert witness tying things together, is the typical approach of patentees fortunate enough to have the wealth of objective indicia of non-obviousness that Kyphon's inventions enjoy in this case.

Not surprisingly, none of the cases cited by DOT requires that objective evidence of non-obviousness must be in the form of expert testimony. The common strategy that certain legal elements be supported with expert opinion testimony does not preclude presentation of other testimony that provides a factual basis for such opinions. Nor does it mean that such objective evidence must be established through a single witness' testimony.[1] Case law shows just the opposite. *See, e.g.*, *WMS Gaming, Inc. v. Int'l Game Tech.*, 184 F.3d 1339, 1360 (Fed. Cir. 1999) (affirming district court's finding of non-obviousness based on the factual testimony on objective indicia of an officer of the patentee); *see also Teleflex, Inc. v. Ficosa North America Corp.*, 299 F.3d 1313, 1334 (Fed. Cir. 2002) (holding that evidence that accused infringer sold a substantial number

[1] DOT also asserts that "Kyphon has already conceded that it needs an expert on these matters[.]" D.I. 249, at 6. However, just because Kyphon intends to present expert testimony during trial does not mean that only expert testimony is admissible to establish objective indicia of non-obviousness. Similarly, DOT's intent to present its own expert on the issue of infringement does not preclude DOT from presenting other witnesses to testify on factual matters relating to infringement, such as how the accused device works.

of accused products was evidence of commercial success that supported jury's finding of non-obviousness).

Moreover, in this case, DOT's argument that any testimony regarding objective indicia of non-obviousness must be deemed expert opinion, is both wrong and disingenuous. It is wrong because Dr. Halliday will simply testify based upon her first-hand knowledge and use of Kyphon's commercial embodiment; whereas other testimony—from the expert engaged by Kyphon, Dr. Marks—will supply the link between the commercial embodiment and the claimed invention.[2] DOT's position is also disingenuous because there is actually no dispute at all that the Kyphon devices (i.e., as used in kyphoplasty procedures) embody asserted claims from each of the patents-in-suit – indeed, DOT has already ***stipulated*** to this fact. **[D.I. 247 (Proposed Pretrial Order, App. 1, at ¶9.).][3]**

Even to the extent Dr. Halliday's testimony could be construed as providing some type of opinion testimony, fact witnesses are not completely barred from offering *any* opinion testimony. Under FRE 701, any lay witness can testify in the form of opinions or inferences which are "rationally based on the perception of the witness" to the extent such testimony is based upon first-hand knowledge and not specialized knowledge gained from training or education. Indeed, if there were someone in Dr. Halliday's office who had similar knowledge of every patient treated by the various methods, that person could

[2] Moreover, if DOT really intends to present a story that doctors perform kyphoplasty, and patients want to be treated with kyphoplasty, only because of shrewd marketing or some other business consideration unrelated to the merits of the claimed invention, DOT is free to cross examine the witnesses on that subject.

[3] "Kyphon, through the sales of and instruction regarding KyphX IBTs and related devices, practices one or more asserted claims in U.S. Patent Nos. 4,469,888; 5,108,404; and 5,235,043B1."

give the same testimony without being a doctor, and without being accused of giving improper "expert" testimony. Such testimony is analogous to that offered in *Lightning Lube, Inc. v. Witco Corp.*, 4 F.3d 1153, 1175 (3d Cir. 1993), which admitted an owner's opinion testimony on damages issues because it was based on his knowledge and participation in the day-to-day affairs of his business.[4] As noted by the Advisory Committee,

> [s]uch opinion testimony is admitted not because of experience, training or specialized knowledge within the realm of an expert, but because of the particularized knowledge that the witness has by virtue of his or her position in the business. The amendment does not purport to change this analysis. Similarly, courts have permitted lay witnesses to testify that a substance appeared to be a narcotic, so long as a foundation of familiarity with the substance is established. *See, e.g., United States v. Westbrook*, 896 F.2d 330 (8th Cir. 1990) (two lay witnesses who were heavy amphetamine users were properly permitted to testify that a substance was amphetamine; but it was error to permit another witness to make such an identification where she had no experience with amphetamines). Such testimony is not based on specialized knowledge within the scope of Rule 702, but rather is based upon a layperson's personal knowledge.

FED. R. EVID. 701 advisory committee's note to 2000 amendment. The important distinction, therefore, between opinions being offered under FRE 701 versus 702 is whether the opinions are based upon first-hand knowledge, as opposed to being based upon some special training or education. Thus, Dr. Halliday's testimony, even to the extent it could be construed as opinion or inference, would be admissible as lay opinion based upon her first-hand knowledge of her own patients.

[4] *See, e.g., Samples v. City of Atlanta*, 846 F.2d 1328 (11th Cir. 1988) (ruling admissible lay opinion from a police department employee witness regarding police policy and practice based on his personal knowledge).

2. Probative Value of Dr. Halliday's Testimony is not Substantially Outweighed by "Unfair Prejudice" or "Needless Presentation of Cumulative Evidence"

DOT also seeks to preclude Dr. Halliday's testimony based on Rule 403. But the only supposed "prejudice" asserted by DOT is being somehow harmed by the quantity of Kyphon's witnesses.[5] Even this point is undermined by Kyphon's voluntary decision to pare back its case by not presenting Dr. Loguidice, another surgeon who was prepared to testify in this matter regarding his experiences. The truth is, there is a long list of doctors who stand ready to praise Kyphon's claimed invention. Kyphon respectfully believes that it should be entitled (within, of course, whatever reasonable time limits the Court wishes to impose on both sides) to present at least one such doctor, aside from the expert engaged by Kyphon, to best present its case to the jury. DOT's apparent belief that it can limit Kyphon's case to the same, small number of witnesses that DOT can muster has no basis in the rules or in fairness.

DOT also argues that Dr. Halliday's testimony will not be helpful "in any way" to the jury because it will be duplicative of testimony from Kyphon's expert, Dr. Marks. This argument is flawed. First, Dr. Halliday's testimony on objective indicia of non-obviousness is not the same as Dr. Marks's testimony. The two witnesses' testimony will corroborate and coordinate with each other, but Dr. Halliday will be talking exclusively from her personal experience, and those experiences are, of course, unique to her.

Moreover, DOT will clearly try to attack Dr. Marks on bias grounds because he is an expert engaged by Kyphon who has spent many, many hours studying relevant

[5] DOT acknowledges that Kyphon will not be presenting the testimony of Dr. Loguidice with regard to objective indicia of non-obviousness. D.I. 249, at 2. However, it then inexplicably keeps saying that Kyphon is offering ***three*** witnesses on objective evidence of non-obviousness. *See, e.g., id.* at 3, 8.

materials and working on this case. Indeed, these "bias" issues comprised a large proportion of DOT's deposition of Dr. Marks. Dr. Halliday, on the other hand, is simply a third party speaking from her experiences with the technology at the heart of this case. Her testimony will be helpful to the jury in forming a clearer understanding of facts supportive of the testimony of Kyphon's expert witness, and is highly probative of the issue of non-obviousness, based on her own personal experiences. *Gambro Lundia AB v. Baxter Healthcare Corp.*, 110 F.3d 1573, 1579 (Fed. Cir. 1997) ("[O]bjective indicia may often be the most probative and cogent evidence of nonobviousness in the record.") (internal quotation marks and brackets omitted).

Further still, simply because some portions of two witnesses' testimonies may relate to the same ultimate issue does not mean that their testimonies are duplicative. Under DOT's rationale, DOT should not be allowed to put any fact witnesses on with regard to the issue of infringement or validity because its expert, Dr. Mitchell, is going to testify on these issues. That objection, however, would be silly. DOT, not surprisingly, cites no law that precludes the testimony of additional witnesses on Rule 403 grounds just because the testimony relates to the same ultimate issue of fact. Rather, Rule 403 only excludes evidence on the basis of "waste of time, or needless presentation of cumulative evidence," if the probative value of that evidence is "substantially outweighed." Here, no time will be wasted—Kyphon anticipates that Dr. Halliday's testimony will be approximately 15-20 minutes long. And Dr. Halliday's testimony certainly is not "needless" because it provides persuasive factual bases that buttress Dr. Marks's testimony regarding the extensive objective indicia of non-obviousness.

DOT should, therefore, not be allowed to cut away a key and persuasive portion of Kyphon's evidence, particularly where Dr. Halliday will be the only third-party testifying at trial and her testimony will be particularly helpful to the jury in explaining the extensive evidence of objective indicia of non-obviousness that exist regarding the inventions at issue. In short, Kyphon respectfully submits that it should be allowed to present such evidence, and it is ***Kyphon*** that would be unduly prejudiced by exclusion of Dr. Halliday's testimony.

3. DOT Filed its Motion too Late

Finally, DOT's motion *in limine* is untimely. By stipulation, the parties were to file all motions *in limine* by May 10, 2005. DOT filed this motion a full month after the deadline, knowing long before the deadline that Kyphon intended to call Dr. Halliday as a witness at trial. By DOT's own admission, it has known that Dr. Halliday had been identified as a witness for Kyphon since January. D.I. 249, at 2, n.1. For DOT to suggest that it was not until June that it had any clue what Dr. Halliday would testify also strains credibility. Even if true, DOT has no one to blame but itself— it never sought to take Dr. Halliday's deposition (via phone or in-person). DOT did not even ask for the subject matter of Dr. Halliday's testimony until June 2, 2005, almost 5 months after being explicitly told that Dr. Halliday was a witness that Kyphon anticipated presenting at trial. *See* D.I. 249, Ex. A. Thus, there is no excuse for DOT's untimeliness.

For these reasons, Kyphon respectfully requests that the Court deny DOT's motion *in limine* to exclude Dr. Halliday from testifying at trial.

DATED: June 14, 2005

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on June 14, 2005, I electronically filed **KYPHON'S OPPOSITION TO DOT'S UNTIMELY MOTION *IN LIMINE* TO PRECLUDE TESTIMONY FROM DR. HALLIDAY REGARDING OBJECTIVE INDICIA OF NON-OBVIOUSNESS** with the Clerk of Court using CM/ECF which will send notification of such filing(s) to the following:

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