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.	)	

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

Defendants Disc-O-Tech Medical Technologies, Ltd. and Disc Orthopaedic Technologies, Inc. ("DOT") respectfully submit this motion in limine, pursuant to Rules 701, 702 and 403 of the Federal Rule of Evidence ("FRE"), to preclude testimony from Dr. Halliday regarding objective indicia of non-obviousness.

PRELIMINARY STATEMENT

Kyphon advised this week that it "anticipates presenting testimony from Drs. Halliday and Loguidice regarding objective indicia of non-obviousness (e.g., praise, long-felt need, etc.)." (See E-mail from Thomas Halkowski, dated June 7, 2005, and the e-mail string preceding it, attached hereto as Exhibit A.)[1] On June 10, 2005, during the finalization of the [Proposed] Pretrial Order for this case, Kyphon advised that it will not be presenting the testimony of Dr. Loguidice, but will present testimony from Dr. Halliday. As detailed more fully below, DOT submits that the proposed testimony of this lay witness should be precluded in limine under at least three independent Federal Rules of Evidence.

First, testimony regarding so-called "objective indicia of non-obviousness" (also referred to as "secondary considerations of non-obviousness") is properly expert testimony, involving technical conclusions concerning the prior art and the claimed invention. Indeed, Kyphon intends to present exactly the same testimony from its proposed expert, Dr. Marks. However, in contrast to Dr. Marks, Dr. Halliday has not been identified in this case as an expert witness; she would be a lay witness at trial. FRE 701(c) prohibits such expert testimony by lay witnesses.

Second, even assuming arguendo that the proposed testimony of Dr. Halliday is not expert opinion, the fact of the matter is that Kyphon already will be presenting an expert witness to testify on this same subject matter. The testimony of Dr. Halliday would be duplicative of the testimony of Kyphon's expert, Dr. Marks. Such redundant testimony would serve no legitimate

[1] While Kyphon contends that these witnesses were listed in Kyphon's witness list provided in January 2005 (which is true), that list contained 23 potential witnesses. (See Exhibit B hereto.) It was not feasible or sensible for DOT to travel around the country deposing every single person on Kyphon's witness list. Kyphon's initial trial witness list, filed with the initial pretrial order on May 12, 2005, contained 10 live witnesses, including these two doctors. DOT did not learn the subject matter of their testimony until June 7, 2005, earlier this week, in response to DOT's inquiry immediately after receiving Kyphon's pared down trial witness list.

purpose in the trial, and would certainly not be helpful to the jury in deciding the case. For these reasons, under FRE 701(b), which prohibits unhelpful opinions by lay witnesses, the opinions of Dr. Halliday are inadmissible.

Third, not only would the proposed testimony be unhelpful to a jury, its only effect would be to improperly and unfairly prejudice DOT by making it appear to the jury that Kyphon is presenting three times more evidence than it actually is presenting. Moreover, DOT would have to waste time and resources presenting cumulative evidence in rebuttal to each of the three proposed witnesses. These considerations warrant exclusion under FRE 403, which allows for preclusion of even relevant evidence on grounds of prejudice, confusion or waste of time.

ARGUMENT

A. Scientific or Technical Opinions by Lay Witnesses Are Inadmissible

FRE 701 governs "opinion testimony by lay witnesses." The rule was amended in 2000 to explicitly prohibit lay opinions that are "based on scientific, technical, or other specialized knowledge within the scope of Rule 702."[2] FRE 701(c); see Advisory Committee Notes to 2000 Amendment of FRE 701 ("The amendment makes clear that any part of a witness' testimony that is based upon scientific, technical, or other specialized knowledge within the scope of Rule 702 is governed by the standards of Rule 702 and the corresponding disclosure requirements of the Civil and Criminal Rules.").

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[2] The full text of Rule 701 is as follows: "If the witness is not testifying as an expert, the witness' testimony in the form of opinions or inferences is limited to those opinions or inferences which are (a) rationally based on the perception of the witness, (b) helpful to a clear understanding of the witness' testimony or the determination of a fact in issue, and (c) not based on scientific, technical, or other specialized knowledge within the scope of Rule 702."

In turn, FRE 702, which governs "testimony of experts," provides stringent rules requiring proper qualification of any proposed expert, as well as sufficiently supported testimony based on reliable scientific principles and methods:

> "If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based on sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case."

The purpose of the amendment to FRE 701 was specifically to avoid what Kyphon is attempting to do in this case – i.e., circumvent the strict rules governing expert testimony:

> "Rule 701 has been amended to eliminate the risk that the reliability requirements set forth in Rule 702 will be evaded through the simple expedient of proffering an expert in lay witness clothing. Under the amendment, a witness' testimony must be scrutinized under the rules regulating expert opinion to the extent that the witness is providing testimony based on scientific, technical, or other specialized knowledge within the scope of Rule 702. By channeling testimony that is actually expert testimony to Rule 702, the amendment also ensures that a party will not evade the expert witness disclosure requirements set forth in Fed. R. Civ. P. 26 and Fed. R. Crim. P. 16 by simply calling an expert witness in the guise of a layperson."

Advisory Committee Notes to 2000 Amendment of FRE 701 (citations omitted); see Collins v. Prudential Inv. and Retirement Services, 119 Fed. Appx. 371, 379-380 (3d Cir. 2005) (upholding district court ruling that a doctor, who was not qualified as an expert, could not provide expert opinion testimony).

There is no question here that Kyphon intends to present, through a lay witness, opinion testimony based on scientific, technical or other specialized knowledge within the scope of FRE 702. In order for Dr. Halliday to testify about secondary considerations of nonobviousness, she will necessarily have to opine on the supposed qualities of the claimed invention as compared to

purported deficiencies in the prior art. For example, to establish that there was a long-felt but unresolved need for the claimed invention, Kyphon would need to show that, inter alia, there was a recognized and persistent technical problem in the prior art, which was unresolved by others in the same field, but yet was resolved by the claimed invention. See Markman v. Lehman, 987 F. Supp. 25, 43 (D.D.C. 1997) ("Establishing a long-felt need requires a showing that others skilled in the art in fact perceived a need and that this perception persisted over a long period of time without resolution by the prior art.") (citation omitted), aff'd, 178 F.3d 1306 (Fed. Cir. 1998) (unpublished); Sjolund v. Musland, 847 F.2d 1573, 1582 (Fed. Cir. 1988) ("[W]e are constrained, as was the jury, to consider whether the claimed invention satisfied a long felt need, or solved problems where others had failed[; b]ecause the lattice construction of Sjolund's tanner board is not part of his claimed invention, the advantages ascribed to the lattice construction are irrelevant in terms of the obviousness analysis.") (emphasis in original).

In that regard, Kyphon would need to present at least the following expert opinions: (1) identification of prior art that sought, but failed, to address a recognized and persistent technical problem, (2) how attempted solutions did not adequately resolve the problem, and (3) how the features of the invention as claimed did adequately resolve the problem. See id. Such technical analyses of the prior art and the claimed invention is necessarily based on "scientific, technical, or other specialized knowledge within the scope of Rule 702," and is not properly the subject of lay witness testimony.

Likewise, to establish commercial success, an expert opinion is required with respect to whether a product or method enjoyed commercial success (compared to competitors) as a direct result of the presence of the claimed invention. See Cable Elec. Products, Inc. v. Genmark, Inc., 770 F.2d 1015, 1027 (Fed. Cir. 1985) ("[F]or commercial success of a product embodying a

claimed invention to have true relevance to the issue of nonobviousness, that success must be shown to have in some way been due to the nature of the claimed invention, as opposed to other economic and commercial factors unrelated to the technical quality of the patented subject matter. Thus, a 'nexus is required between the merits of the claimed invention and the evidence offered, if that evidence is to be given substantial weight enroute to [a] conclusion on the obviousness issue.'") (citations omitted), rev'd on other grounds by Midwest Industries, Inc. v. Karavan Trailers, Inc., 175 F.3d 1356 (1999); Sandt Technology, Ltd. v. Resco Metal and Plastics Corp., 264 F.3d 1344, 1355 (Fed. Cir. 2001) ("nexus was not proven between this patented feature and the substantial sales"); Vandenberg v. Dairy Equipment Co., 740 F.2d 1560, 1567 (Fed. Cir. 1984) ("A nexus must be established between the merits of the claimed invention and the evidence of commercial success before that issue becomes relevant to the issue of obviousness.") (citations omitted). There is simply no way a lay witness can reasonably issue such an opinion.

Indeed, Kyphon has already conceded that it needs an expert on these matters; it has identified an expert, Dr. Marks, to testify about the same exact subject matter. Dr. Marks has submitted an expert report in which he specifically opines on secondary considerations of nonobviousness, and cites hundreds of production numbers as alleged support for his opinions. (See Rebuttal Expert Witness Report of Michael Marks, M.D., dated March 23, 2005, at pp. 26-28, attached hereto as Exhibit C.)

Thus, it is clear that the proposed testimony of Dr. Halliday falls squarely within FRE 701's prohibition against opinions "based on scientific, technical, or other specialized knowledge within the scope of Rule 702." Kyphon seeks to introduce Dr. Halliday's opinion without having to meet any of the requirements of expert testimony, and for this reason alone, the proposed testimony should be precluded in limine.

B. Unhelpful Opinions Are Inadmissible

Assuming for argument's sake that the opinions of Dr. Halliday are not inadmissible under FRE 701(c), the opinions should be precluded under FRE 701(b), which only allows opinions by lay witnesses if they are "helpful to a clear understanding of the witness' testimony or the determination of a fact in issue."

In this case, the proposed testimony of Dr. Halliday would not be helpful in any way to a jury. As an initial matter, it would be duplicative of the proposed testimony of Kyphon's expert, Dr. Marks. (As discussed above, Dr. Marks has submitted an expert report in which he purportedly relies on hundreds of documents in support of his opinions regarding secondary considerations.)

There is simply no legitimate reason for admissibility of the opinions of Dr. Halliday, and therefore, preclusion is mandated by FRE 701(b).

C. Unduly Prejudicial and/or Cumulative Opinions Are Inadmissible

Finally, regardless of FRE 701, the proposed testimony of Dr. Halliday is inadmissible under FRE 403, which permits a Court to preclude evidence "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."

Apart from being unhelpful to a jury, the duplicative testimony of Dr. Halliday would be unduly and unfairly prejudicial to DOT. The only conceivable purpose for the testimony of this doctor is to bombard the jury with cumulative opinions about how the claimed invention would not have been obvious. Under this strategy, Kyphon hopes to improperly persuade a jury with the quantity of its witnesses, rather than the quality of the evidence.

Moreover, such duplicative testimony would be a waste of time for everyone involved, including the Court, the jury and DOT. Of particular significance to DOT is the fact that it would have to spend significant portions of its allotted case presentation time cross-examining three different witnesses on the same subject matter.

These independent reasons warrant preclusion under FRE 403.

CONCLUSION

For the foregoing reasons, DOT's motion in limine to preclude the proposed testimony of Dr. Halliday should be granted in all respects.

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June 10, 2005

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CERTIFICATE OF SERVICE

I, Maryellen Noreika, hereby certify that on June 10, 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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I also certify that copies were caused to be served on June 10, 2005 upon the following in the manner indicated:

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