UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF INDIANA
FORT WAYNE DIVISION

ZIMMER TECHNOLOGY, INC., and ZIMMER, INC.	)	
Plaintiffs,	)	
v.	)	CIVIL NO. 3:02cv425
HOWMEDICA OSTEONICS, CORP.	)	
Defendant.	)	

OPINION AND ORDER

This matter is before the court on "Motion in Limine No. 1 (Non-Infringement)" filed by Howmedica Osteonics, Corp. ("Howmedica") on September 10, 2008.

Discussion

Howmedica requests an order precluding Zimmer from making any arguments or references at trial (either through statements of counsel or by eliciting testimony from witnesses) that Howmedica's FDA filings are relevant to the determination of infringement in a means-plus-function equivalents analysis. Howmedica argues that such arguments or references are legally erroneous, irrelevant, contrary to the law, and risk substantial prejudice to Howmedica, including a high risk of juror confusion.

During the development of its accused products, Howmedica submitted an FDA application for a predecessor prototype device that used a Morse taper connection, which design Howmedica eventually rejected in favor of a device using a thread-and-locking-nut connection. Howmedica did not submit a new FDA application for the threaded connection because it did not believe that such an application was necessary under the FDA's regulatory requirements.

One issue in this case is whether Howmedica's threaded connection infringes certain

claims of U.S. Patent No. 5,290,313 ("the '313 patent") under a means-plus-function equivalents analysis. Howmedica claims that Zimmer has indicated that it may argue that Howmedica's failure to submit a new FDA application for a device with a threaded connection somehow establishes equivalency under 35 U.S.C. § 112, paragraph 6. According to Howmedica, Zimmer should not be allowed to make such an argument because courts have repeatedly held that FDA submissions do not constitute admissions or evidence related to alleged infringement in patent cases.

In response, Zimmer states that it does not intend to offer at trial any arguments that equate FDA and patent law. However, Zimmer objects to Howmedica's position that any arguments or references at trial regarding Howmedica's FDA filings are irrelevant to the determination of infringement. Zimmer argues that Howmedica has put these filings at issue because Howmedica seeks to show that "Howmedica's own independent product development, and Howmedica's rejection of a Morse taper connection for safety and other reasons, reflects an appreciation of substantial differences between Morse taper and thread-and-locking-nut connections." (DE 532 at 6).

According to Zimmer, because Howmedica's FDA filings contain admissions including Howmedica's own testing of the safety of the Morse taper connection, they are not only relevant but highly probative. Zimmer claims that "contrary to Howmedica's skewed interpretation of the case law" statements to the FDA that bear on relevant facts are admissible as evidence of infringement. Abbott Labs. v. Baxter Pharm. Prods., Inc., No. 01 C 1967, 2004 WL 2496459, at *4 (N.D. Ill. Nov. 3, 2004). In Abbott, the court held that statements made by the plaintiff to the FDA about the accused product were relevant for purposes of determining infringement. Id. at

*3. The court concluded that unlike cases that did not permit admission of statements of "substantial equivalence" to the patentee's product because such statements improperly compared the accused products to the patentee's products, the evidence at issue in Abbott related only to the comparison of "the potentially infringing product to the already construed claims." Id. at *4.

However, as Howmedica points out in reply, the FDA submission at issue in Abbott was not a 510(k) submission (as in the present case), but a letter arguing patent infringement by a competitor that filed an Abbreviated New Drug Application ("ANDA"), which letter contained a certification of the non-infringement of the patent at issue. As the letter only compared the accused product to the patent claims at issue, rather than comparing the product to other products for purposes of regulatory safety and efficacy as in a 510(k) submission, Abbott does not apply.

Additionally, as Howmedica notes, Zimmer has failed to distinguish Howmedica's legal authorities. In Univ. of Fla. Research Foundation, Inc. v. Orthovita, Inc., No. 1:96cv82-MMP, 1998 U.S. Dist. LEXIS 22648, at *79 (N.D. Fla. Apr. 20, 1998)(unpublished), the court explicitly stated that it "cannot use the FDA 510(k) notification in considering infringement by equivalence." Id. Similarly, in CardioVention, Inc. v. Medtronic, Inc., 483 F. Supp. 2d 830, 840-41 (D. Minn. 2007), the court stated that the 510(k) submission was minimally relevant to a non-patent issue, but not relevant at all to the issue of trade secret misappropriation.

Accordingly, this court will grant Howmedica's motion in limine, and rules that Zimmer may not make any arguments or references related to Howmedica's FDA filings, the statements made therein, and related testimony.

Conclusion

Based on the foregoing, Howmedica's Motion in Limine No. 1 (Non-Infringement) [DE 515] is hereby GRANTED.

Entered: November 25, 2008.

s/ William C. Lee
William C. Lee, Judge
United States District Court