

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA**

IN RE ST. JUDE MEDICAL, INC., :
SILZONE HEART VALVES PRODUCTS :
LIABILITY LITIGATION : **MDL DOCKET NO. 1396**

JOINT STATUS CONFERENCE REPORT

(Status Conference—November 12, 2002, 5:00 p.m.)

The parties have met and conferred and submit this status report to the Court.

1. DISCOVERY MATTERS

A. Document and Written Discovery Issues Outstanding

Plaintiffs have raised several document and written discovery issues on which counsel have conferred a number of times since the beginning of September 2002. The following discovery issues remain outstanding:

1. St. Jude Medical's 21 C.F.R. sec. 820.198 "complaint files" concerning Silzone valves.
St. Jude Medical responds that these documents will be produced in response to Plaintiffs' Second Request for Production of Documents "on a rolling basis," beginning on or about November 14, 2002;
2. The personal files of St. Jude Medical's medical director, Dr. Frater, which had not previously been collected from Dr. Frater's New York office. St. Jude Medical responds that it will collect and produce same;

3. Photographs and microphotographs taken in connection with animal studies of the Epic valve, a bioprosthetic device which was not approved or sold in the United States that also had a Silzone-coated sewing cuff; St. Jude Medical responds that although these photographs are not the subject of any pending or past document request, St. Jude Medical has agreed to make available for inspection 2,200 histology slides and reproduce 360 35mm slides at plaintiffs expense, but has indicated that duplication will be expensive; Plaintiffs are reviewing the cost issue, and have requested St. Jude Medical's index to the slides;
4. Any photographs and microphotographs taken in connection with any animal studies conducted on Silzone-coated annuloplasty rings, or confirmation that none exist; St. Jude Medical responds that although these photographs are not the subject of any pending or past document request, St. Jude Medical will duplicate all responsive photographs at plaintiffs' expense;
5. Documents relating to Dr. Cameron's pathology review of the chronic animal study of the Epic valve, or confirmation that none exist; St. Jude Medical responds that it has produced all responsive documents in its possession;
6. Missing source coding for several thousand discovery documents already produced; St. Jude Medical responds that it has provided all source coding for the documents it has produced;
7. Documents addressing determinations of silver levels in tissue of animals, such as in the Epic valve animal study; St. Jude Medical responds that it has produced all responsive

documents in its possession;

8. Additional documents and available raw data concerning the *in vivo* and *in vitro* studies performed on Silzone-coated annuloplasty rings; St. Jude Medical responds that it has produced all documents in its possession;
9. Results of search of email electronic backup tapes; St. Jude Medical responds that it does not understand what plaintiffs are referring to here;
10. Additional submissions to regulatory authorities in the U.K., Europe, Australia, and Canada regarding other Silzone products; St. Jude Medical responds that it has produced all responsive documents in its possession.

In addition to the foregoing promised documents and information, the parties have not yet reached final agreement with respect to the following outstanding discovery about which counsel has conferred:

11. Color copies of Silzone advertising documents; St. Jude Medical has agreed to provide these documents to plaintiffs;
12. Copies of St. Jude Medical's responses to generic interrogatories propounded in the Ramsey County cases;
13. A description of FER files withheld from production; St. Jude Medical recently provided a list, although the descriptions involve numerical codes for which no key has yet been provided; St. Jude Medical responds that it has directed plaintiffs to the numerical codes which had been provided previously;
14. Documents, in addition to initial submissions, sent to or received from regulatory authorities

in the U.K., Europe, Australia, and Canada regarding Silzone products; St. Jude Medical responds that these documents were only recently requested and will be produced in response plaintiffs' Second Request for Production of Documents;

15. Designation of one or more (as necessary) Custodians of Records who will verify the manner and completeness of St. Jude Medical's document production;
16. Supplementation and verification of St. Jude Medical's unverified responses to Plaintiffs' preemption interrogatories. St. Jude Medical takes the position that referring Plaintiffs to certain discovery CDs containing documents or ranges of documents that may contain responsive information, as well as providing detailed narrative responses, are appropriate parts of a complete response; Plaintiffs' position is that FRCP 33(d) requires a substantially greater degree of specificity where references to documents are offered in lieu of a complete narrative response, especially where, as here, the number of documents ranges in the tens of thousands and involves several hundred pages of documents, and includes references to extensive third-party productions without any standards index. St. Jude Medical responds that it gave extremely detailed narrative responses to plaintiffs' preemption interrogatories, as well as citations to supporting evidence. St. Jude Medical stands by those responses as drafted. Plaintiffs also have raised with St. Jude Medical the issue of preemption Interrogatory responses that attempt to state the mental impressions or actions of third parties without any citation or other reasonable record reference, if any, that supports the assertion. St. Jude Medical stands by its responses and submits that it has provided all of the appropriate citations.

Finally, plaintiffs contend that St. Jude Medical is contending that many of its basic internal corporate documents, such as minutes of meetings of its Board of Directors or Executive Committee and Standard Operating Procedures for adverse event reporting during the relevant time frame in which the Silzone products were developed, marketed, and sold, were not required to be produced pursuant to St. Jude Medical's Rule 26 obligations or to any of Plaintiffs' discovery. Plaintiffs submit to the Court that Standard Operating Procedures for handling adverse events concerning St. Jude Medical's products were generally covered by Plaintiffs' discovery requests served months ago and are materials well within St. Jude's Rule 26 obligation to produce.

Plaintiffs intend to move to compel production of all such outstanding discovery to the extent it is not voluntarily produced promptly.

St. Jude Medical responds that it has produced copies of the operative Standard Operating Procedure regarding Field Experience Reports. St. Jude Medical further responds that plaintiffs have never requested St. Jude Medical to produce minutes of meetings of its Board of Directors or Executive Committee.

B. Subpoena of Sulzer Carbomedics, Inc.

Plaintiffs' counsel has contacted counsel for Sulzer Carbomedics regarding its (untimely) objections to Plaintiffs' document subpoena issued from the United States District Court for the Western District of Texas on August 29, 2002. (The Court will recall that Sulzer had previously objected to an earlier identical subpoena issued from the District of Minnesota on purported jurisdictional grounds.) Sulzer's objections on confidentiality and trade secret grounds were addressed by offering to enter into a confidentiality agreement, but Sulzer's counsel has thus far not been responsive to Plaintiffs' counsel's offer. Moreover,

Sulzer further maintains that Plaintiffs must pay for Sulzer to hire a former employee to find and produce its own responsive documents. Sulzer has not responded to a telephone message and a letter from Plaintiffs' counsel on these matters, but has instead sent a letter to the Court setting forth its position

At the last Status Conference on September 24, 2002, the Court indicated that it would, if necessary, address any remaining issues regarding Sulzer's objections to Plaintiffs' document subpoena. It appears that this will be necessary.

C. Costerton Custodian of Records Deposition

On October 23, 2002, St. Jude took a "Custodian of Records" deposition of Dr. J. William Costerton, an independent biofilm expert and consultant to the MDL plaintiffs and to certain of the individual plaintiffs' counsel in U.S. and Canadian litigations. Appearing as counsel for St. Jude was an attorney from Colorado who had appeared as local counsel in one of the Colorado class actions but who had not previously appeared as counsel of record in this consolidated class action case, nor has he been introduced to the Court. No member of the Crosby, Heafey firm attended the deposition. The Colorado attorney proceeded to question Dr. Costerton for approximately three-and-a-half hours. The Colorado attorney noted on the record, over objection, that "Dr. Costerton may be an expert witness in some proceedings involving my client's heart valves. We're certainly entitled to know about all the investigations that he has conducted, which may form the basis of his testimony. And that includes observations that are favorable and unfavorable to my client, and favorable and unfavorable to the Plaintiff. So we intend to get everything."

Plaintiffs object to the taking of any expert witness depositions under the guise of a routine

Custodian of Records notice, and outside of the procedures set forth in Pretrial Orders #20 and #21. Plaintiffs further object to Defendant's questioning of any non-testifying expert consultant to the MDL plaintiffs or any individual plaintiffs' counsel. Plaintiffs seek the assurances of Defendant's counsel that such practices will not continue, or the instruction of the Court on these issues. Plaintiffs also object to the participation of any attorney not from the Crosby, Heafey firm at a deposition or any proceeding unless such counsel has been admitted as counsel for the Defendants in the MDL.

St. Jude Medical disputes plaintiffs' characterization of what transpired at Dr. Costerton's deposition. The reason the deposition was lengthier than expected is because Dr. Costerton had not produced all documents in his possession that were responsive to St. Jude Medical's subpoena. It should be noted for the record that Plaintiffs' State Liaison counsel, Patrick Murphy, was present at Dr. Costerton's deposition and was certainly capable of moving for a protective order if the questioning was as plaintiffs represent. Dr. Costerton also had his own counsel present at the deposition.

D. Deposition of James Ladner

Plaintiffs' counsel notified St. Jude Medical's counsel of their intention to depose James W. A. Ladner, in-house counsel at St. Jude Medical, as a fact witness. Plaintiffs contend that Mr. Ladner's name appears upon and within many documents produced by St. Jude Medical in the litigation. St. Jude Medical disputes this and submits that Mr. Ladner's involvement as a "fact witness" was very limited. As such, St. Jude Medical has objected to an unrestricted deposition of Mr. Ladner. Plaintiffs' counsel have identified some intended areas of questioning, including without limitation St. Jude Medical's pre- and post-marketing activity; involvement with outside consultants; pre-litigation email communication; negotiations with the Spire corporation; and dealings with third parties relating to reported heart valve problems. Plaintiffs believe that

St. Jude Medical's ability to interpose any appropriate privilege objections at Mr. Ladner's deposition, if St. Jude Medical deems such necessary, should obviate any problem with Mr. Ladner's deposition going forward.

St. Jude Medical objects to plaintiffs' request to take an unrestricted deposition of Mr. Ladner who is an Associate General Counsel at St. Jude Medical and primarily responsible for the direction of defense efforts in this litigation. Although St. Jude Medical recognizes that Mr. Ladner is not immune from being deposed, well established federal law places the burden on plaintiffs to prove (1) that no other means exist to obtain the information than to depose Mr. Ladner, (2) the information sought is relevant and non-privileged, and (3) the information is crucial to the preparation of the case. Shelton v. American Motors Corp., 805 F.2d 1323 (8th.Cir. 1986). St. Jude Medical is amenable to producing Mr. Ladner for deposition provided that an agreement is reached prior to the deposition between the parties to appropriately limit the scope of the questioning to crucial non-privileged matters in which there is no other means to obtain the information sought.

After numerous discussions in an effort to meet and confer, the parties reached an impasse and will seek the Court's guidance on this issue.

E. New Discovery Received from AVERT

At the end of October, Plaintiffs received additional documents from AVERT. Copies have been sent to St. Jude Medical's counsel in accordance with third-party protocol.

F. Schedule of Remaining Preemption Discovery

Counsel for Plaintiffs have notified defense counsel of the deposition sequence and timing for completion of preemption discovery. Defendant has scheduled the deposition of the first noticed witness,

Alan Flory, for November 12 -13. Diane Johnson is scheduled for November 19. Following the review by Dr. Wilson of the pathology slides recently produced by St. Jude Medical, Plaintiffs intend to depose Barbara Illingsworth, Katherine Tweden, Douglas Cameron, Maggie Walner and Tim Chase. Thereafter, Plaintiffs will serve a Rule 30(b)(6) Notice of Designated Representative deposition which will reflect the areas of inquiry previously provided to Defendant's counsel and the Court. Plaintiffs hope to be in a position to complete preemption discovery by the end of December.

2. MOTION TO PROTECT CONFIDENTIALITY DESIGNATIONS; DECLASSIFICATION OF CLASS CERTIFICATION MOTION

St. Jude Medical has moved to "protect confidentiality" of certain documents produced in the litigation, and about which counsel have met and conferred. Plaintiffs have filed a response to St. Jude Medical's motion, and moved to declassify the briefing on the class certification motion, as previously discussed with the Court. St. Jude Medical has indicated that it wants to file a reply brief and requires a brief extension of time in which to do so. No hearing date has been set.

3. STATUS OF CANADIAN LITIGATION

The presiding court in Ontario issued an opinion ruling on St. Jude Medical's Daubert-type motion on October 29, 2002. A copy is attached for the Court's reference. Although the Canadian court struck certain portions of plaintiffs' expert affidavits, it also ruled that the case proceed to a class certification hearing.

Canadian plaintiffs' national class counsel has requested that the discovery issue of the production of sheep hearts and organs from the five- and ten-week Masters Series Silzone sheep studies be raised, although no formal discovery request for this material has ever been propounded in Canada or in these proceedings. During informal discussions, St. Jude Medical 's counsel in the MDL has represented to Plaintiffs' counsel that organs were not preserved from the Masters Series- animal studies.

Canadian plaintiffs' counsel has also asked that their concern be conveyed to the Court regarding the subpoena and questioning of their consultant, Dr. Costerton, addressed in Section 1.C., above.

4. REPORT ON STATE AND FEDERAL COURT FILINGS

St. Jude Medical's most recent report on state and federal court filings was forwarded to the Court by electronic mail on October 27, 2002. The totals reported are 39 federal court filings (up from 37) and 108 state court filings (up from 102). Class counsel is aware of one additional Ramsey County case filed after October 27, 2002.

5. MDL STATUS LETTER TO COUNSEL

Class counsel is drafting a letter to all MDL counsel updating them on events in the MDL and advising them of St. Jude Medical's efforts to take the case-specific depositions of plaintiffs and their health care providers before December 31, 2002.

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Dated: November 12, 2002

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