

**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

(Telephonic Status Conference—December 16, 2002, 12:30 p.m.)

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

1. DISCOVERY MATTERS

A. Discovery Issues Outstanding

The parties have conferred on several discovery issues since the last status conference. The status of outstanding discovery issues includes the following:

- a. 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 has recently produced Dr. Frater's non-electronic documents and is working on producing Dr. Frater's electronic documents.
- b. EPIC valve animal study pathology slides. Plaintiffs have requested that these 2,200 slides be couriered to their expert, Dr. Wilson, in Toronto, as had been done previously in this case with pathology slides relating to the Masters Series animal studies. St. Jude Medical is presently unwilling release the slides for inspection outside of its Minnesota facilities because the EPIC valve is still being marketed. St. Jude Medical responds that (1)

because it may be asked by regulatory authorities to make such slides available for inspection at any time, and (2) because it has no backups in case the slides are damaged, St. Jude Medical cannot simply release custody of the slides. Notwithstanding, St. Jude Medical is willing to make the slides available for Dr. Wilson to review in Minneapolis. St. Jude Medical possesses an index to the slides which identifies the animal from which the pathology was obtained and whether or not that animal was implanted with an EPIC valve with Silzone cuff or a conventional cuff. In the Canadian class action case, St. Jude Medical advised the presiding court that Dr. Wilson's concerns regarding the whereabouts of his pathology slides that he sent to Dr. Fredrick Schoen of Harvard (a forensic witness of St. Jude Medical in the Canadian action) were not of any moment because such slides "can be recreated by Dr. Wilson if necessary from tissue blocks that he has in his possession." The parties are exploring if there can be an agreed upon procedure by which Dr. Wilson may select for review a smaller number of the slides outside of the State, or may review all the slides transmitted in small groups over time. Plaintiffs contend that the cost and expense of having Dr. Wilson go to Minneapolis to review the slides is prohibitive and makes the review in this manner unworkable. Plaintiffs suggest that the slides should be delivered to him on a rolling basis and if the FDA should request a specific slide then in the possession of Dr. Wilson, he will immediately provide same to the FDA.

- c. St. Jude Medical's privilege log of withheld and redacted documents. St. Jude Medical recently produced Volumes II and III of its privilege log. St. Jude Medical will complete its privilege log by December 31, 2002.
- d. Complaint Files. St. Jude Medical will complete its production of its Silzone product Complaint Files by December 16, 2002.
- e. Designation of one or more (as necessary) Custodians of Records who will verify the manner and completeness of St. Jude Medical's document production. St. Jude Medical responds that the document collection effort in this litigation has involved many lawyers and employees of the company and that no one person can be produced to testify as to its completeness. St. Jude Medical objects to a deposition as to the "manner" of the document production effort because such information is attorney work product.
- f. Timing of receipt of the next set of AVERT freeze data.
- g. Supplementation of St. Jude Medical's responses to Plaintiffs' preemption interrogatories. St. Jude Medical recently provided a verification of its responses, as requested by Plaintiffs, though the verification was made on information and belief. With regard to the substance of the responses, 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 that have no standard index. Plaintiffs contend that the state of the objective coding produced by St. Jude Medical also does not permit document titles searches and is highly inaccurate and non-selective as to its coding of document types. St. Jude Medical disputes these contentions and 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 and submits same to the Court for review.

- h. St. Jude Medical submitted to the Court by facsimile on December 10, 2002 a redacted document referenced in the deposition of Al Flory (Bates No. SJM1790422104) and an accompanying letter requesting an *in camera* review to uphold St. Jude Medical's claim of privileged status for the redacted portions of the document. Plaintiffs have requested St. Jude Medical to produce the referenced document in unredacted form. St. Jude Medical contends that the redacted portion of the letter references a privileged communication between St. Jude Medical and its outside counsel, Steve Kohn.

B. Subpoena of Sulzer Carbomedics, Inc. – Resolved

Plaintiffs' motion to compel production by Sulzer Carbomedics, Inc., calendared for argument at this status conference, has been resolved. Subject to execution of a confidentiality agreement equivalent in form to that used previously in this case for the

document production by Spire Corporation, Sulzer has agreed to produce the requested documents. Plaintiffs will pay for the reasonable copying costs.

C. Subpoena of Dr. Frederick Schoen

Plaintiffs' third-party document subpoena issued by the MDL Court to Dr. Frederick Schoen in Massachusetts remains outstanding. Counsel for Dr. Schoen has interposed numerous objections but expressed strong willingness to meet and confer with Plaintiffs' counsel. He has indicated, however, that scheduling may somewhat impede his ability to confer with Dr. Schoen and participate in further substantive discussions with Plaintiffs until January of next year. Plaintiffs remain hopeful that a satisfactory and timely production arrangement may be worked out with Dr. Schoen, but note that MDL deadlines may require a precautionary motion be brought in time to be heard at the next status conference.

D. Schedule of Remaining Preemption Discovery

Counsel for Plaintiffs have notified defense counsel of the deposition sequence and timing for completion of preemption discovery. Plaintiffs have taken the depositions of Alan Flory, Diane Johnson, and Jonas Runquist. The parties have scheduled, or are working on the scheduling of, Maggie Walner, Tim Chase, Matthew Ogle, Barbara Illingworth, Katherine Tweden, Douglas Cameron, and Daniel Langanki. Thereafter, Plaintiffs will serve a Rule 30(b)(6) Notice of Designated Representative deposition which will reflect the areas of inquiry previously provided to St. Jude Medical's counsel and the Court; a Custodian of Records deposition to verify the completeness of St. Jude Medical's production, which St. Jude Medical objects to for the reasons set forth above; and Requests for Admissions. Plaintiffs hope to be in a position to complete preemption

discovery by mid-February, depending in part on the resolution of outstanding discovery issues.

2. PREEMPTION BRIEFING SCHEDULE

The parties have conferred and agree, subject to certain contingencies, on the following briefing schedule for St. Jude Medical's motion for summary judgment on preemption: Plaintiffs' Opposition on March 21, 2003; St. Jude Medical's Reply on April 4, 2003; hearing in the week of April 7, 2003, as convenient for the Court.

Plaintiffs note that this schedule should be workable, provided that St. Jude Medical does not supplement its submission with additional expert witnesses or expert declarations.

3. STATUS OF RAMSEY COUNTY CASES

St. Jude Medical has reached agreements of settlement with the Ramsey County plaintiffs represented by the Robins Kaplan law firm.

Following a telephonic status conference initiated by counsel for the remaining Ramsey county plaintiffs, Judge Gearin has set the following briefing schedule for St. Jude Medical's motion for summary judgment on preemption: Plaintiffs' Opposition on March 3, 2003; St. Jude Medical's Reply on March 17, 2003; hearing on March 27, 2003.

4. STIPULATION TO EXTEND MERITS DISCOVERY CUT-OFF BY 90 DAYS

In light of the parties agreement on a preemption briefing schedule, the parties have further stipulated to, and seek the Court's approval of, a 90-day extension of the merits discovery cut-off dates set forth in Pretrial Order Nos. 16 and 20.

5. CANADIAN LITIGATION – CLASS CERTIFICATION STATUS

The following is the schedule set by the Court at the November 29th case conference:

1. Plaintiffs are to provide their proposed amended claim (with any new representative plaintiff), and their amended litigation plan within 10 days.
2. St. Jude Medical will provide plaintiffs with a list of depositions conducted in the US proceedings of (a) company witnesses - past and present and (b) experts that have sworn or will be swearing affidavits in Canada.
3. St. Jude Medical will serve any further affidavits by January 20, 2003.
4. Plaintiffs will serve any further affidavits in reply by February 17, 2003.
5. Plaintiffs to make best efforts to identify transcripts they wish to use by no later than February 17, after which parties will discuss terms.
6. Plaintiffs to make best efforts to identify documents from the US productions they wish to use on the motion and cross-exams, by February 17.
7. Cross-exams of experts to be completed by March 31.
8. Plaintiffs' factum (brief) to be served by May 7.
9. St. Jude Medical's factum (brief) to be served by May 20.
10. Class Certification hearing to be held June 2 to 10 (if all days are necessary - counsel thought 1 week would be enough).

6. 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 December 9, 2002. The totals reported are 42 federal court filings (up from 39) and 93 state court filings (down from 108).

ZIMMERMAN REED, P.L.L.P.

Dated: December 13, 2002

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