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1 (In chambers.)

2 THE COURT: Let's have everyone identify
3 themselves, please.

4 MR. COREN: Michael Coren for the PSC, Your
5 Honor.

6 MR. CIALKOWSKI: David Cialkowski also with the
7 PSC.

8 MS. DECKER: Ann Decker from Fredrikson & Byron
9 representing Dr. Schaff. With me is Josh Murphy, in-house
10 counsel for Mayo, also representing Dr. Schaff.

11 MR. MURPHY: Good afternoon, Your Honor.

12 MR. KOHN: This is Steve Kohn and --

13 MS. VAN STEENBURGH: Tracy Van Steenburgh.

14 (Telephone disconnected.)

15 THE COURT: Everyone back. Okay. Let's see. We
16 got everyone identified, correct? Just for the record,
17 this is civil case number 01-1396, In re St. Jude Medical,
18 Incorporated, Silzone Heart Valves Products Liability
19 Litigation.

20 Okay. We've got a discovery matter today. Who
21 is going to begin?

22 MS. DECKER: Your Honor, this is Ann Decker from
23 Fredrikson & Byron, and I think as the party who or the
24 person who raised this issue, perhaps I could begin this
25 afternoon. Josh Murphy and I represent Dr. Schaff.

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1 Dr. Schaff is a cardiac surgeon at Mayo Clinic
2 Rochester and the chair of the division of cardiac surgery.
3 He has also served as the principal investigator for the
4 AVERT study sponsored by St. Jude, and Mr. Coren and I have
5 been communicating about Dr. Schaff's deposition, which has
6 now been scheduled for March 29th.

7 And the issue that brings us here today is the
8 decision by the plaintiffs' steering committee that they
9 will not reimburse Dr. Schaff for his time in giving a
10 deposition. As a result, in representing Dr. Schaff, we're
11 here either seeking reimbursement for his time or for a
12 protective order limiting the questions in his deposition
13 to eliciting only facts and not opinions.

14 MR. COREN: Your Honor, Mike Coren. I'll speak
15 on behalf of the PSC today. Your Honor, our position is
16 that Dr. Schaff as the consultant for St. Jude and the
17 principal investigator for St. Jude clearly falls within
18 the ambit of being a fact witness, and furthermore that
19 under the decisional law of this court, as well as the
20 statutes, the compensation for a fact witness is limited to
21 \$40 under the statute, which we have tendered along with

22 the mileage.

23 Doctors every day are taken as fact witnesses,
24 and there is really nothing unusual about this. We're
25 dealing with a published study which is the principal

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1 linchpin of defendant's defense which has been raised
2 numerous times in front of Your Honor, and we feel that we
3 have a right to take Dr. Schaff's deposition as a fact
4 witness regarding the matters that he did on AVERT and the
5 things that he -- we're advised by St. Jude what he advised
6 them, what was done, what actions were taken and so on and
7 so forth, which clearly under the decisional law, and as I
8 read through the cases Your Honor handed down, the Martino
9 case I think being the first and the Shimek, S-H-I-M-E-K --
10 I apologize if I'm mispronouncing -- but under those cases
11 as I understand, we would never even be able to get
12 reimbursement for these fact witnesses if we paid them more
13 than the \$40.

14 MS. DECKER: Your Honor, this is Ann Decker
15 again.

16 Are you done, Mr. Coren?

17 MR. COREN: Yes, I am.

18 MS. DECKER: If I could, first of all, correct a
19 misstatement of the facts. Dr. Schaff is not a consultant
20 to St. Jude. He was the principal investigator. Any
21 compensation went to Mayo Clinic Rochester. It was

22 reimbursement for the research.
23 There was no compensation, for example, to
24 Dr. Schaff; but in addition, it's inconceivable that
25 Dr. Schaff at a minimum is not a hybrid witness giving both

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1 expert testimony or being asked to give expert testimony
2 under Federal Rule of Evidence 702 with respect to
3 scientific or technical or specialized matters.

4 He clearly will have some testimony that is
5 factual in nature, his involvement in the study, his
6 interaction with individuals at St. Jude and at the
7 University of Pittsburgh, but by the same token, he is an
8 expert by the very nature of his training and what he did
9 as part of this study.

10 This is a significant issue. You may wonder why
11 we're here fighting over a relatively minor amount of
12 money, but this is a significant issue to institutions like
13 Mayo Clinic Rochester who have individuals who are
14 investigators in clinical research trials and who are
15 frequently but through no fault of their own pulled into
16 litigation to testify on behalf of either side, and it is
17 important as a matter of principle that these nonparties
18 not be subjected to undue hardship or burden as a result of
19 the litigation.

20 We agree that plaintiffs have the right to take
21 Dr. Schaff's deposition. That's not the issue at all. We

22 have scheduled a date, and Dr. Schaff will be there. The
23 real issue is, first of all, reimbursement or if the Court
24 determines that Dr. Schaff is a fact witness, we would like
25 to reach an agreement as to the scope of the deposition

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1 which will occur.

2 Currently the plaintiffs have asked for a full
3 day deposition, which seems excessive if Dr. Schaff truly
4 is a fact witness.

5 MR. COREN: Your Honor, if I may, or if you have
6 heard enough, I'll shut up.

7 THE COURT: That's fine. Before I get back to
8 you, Mr. Coren, do Mr. Kohn or Ms. Van Steenburgh have
9 anything you would like to say?

10 MR. KOHN: Your Honor, we view this as a dispute
11 between the Mayo Clinic and the PSC. We really don't have
12 a position. They're the ones who noticed the deposition.
13 We'll certainly be attending. It's inconceivable to me
14 given the scope of his involvement with this trial and the
15 number of published papers that he is not going to be asked
16 a significant number of opinion questions, but we take no
17 position as to this issue.

18 THE COURT: Mr. Coren?

19 MR. COREN: Yes. Your Honor, as in all of these
20 type of things, where an opinion begins and an opinion ends
21 is always somewhat of a slippery slope, but the point here

22 is that St. Jude turned to Dr. Schaff and asked him and
23 several other people around the world to fashion a study.
24 The study is ongoing.
25 There is a certain aspect to that that makes one

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1 wonder whether the study is converted from a efficacy study
2 to an informational to litigational study and who is paying
3 for the ongoing expenses to St. Jude, and St. Jude has
4 claimed litigational privilege of some sort. Exactly
5 offhand I can't recall whether it was work product or what,
6 but my point is is that the study once again is the central
7 component of defendant's defense here.

8 They claim there is no problem with these valves,
9 AVERT so says, except perhaps there was one at one time a
10 PVL. We, on the other hand, question the validity of the
11 study. There is questions that go to how the study was
12 operated.

13 There is also questions that it turns out that
14 when Dr. Eric Bruchart showed up on the scene, who is
15 another one of St. Jude's study consultants who was running
16 a study, they turned to Dr. Schaff regarding whether or not
17 this was a problem or whether Dr. Bruchart was an outlier.

18 All of these issues are things that we need to
19 probe to find out what was going on, what St. Jude -- what
20 St. Jude did or didn't do, and unfortunately Dr. Schaff
21 finds himself at ground zero, you know, in this

22 controversy. So I think that's about, you know, what I

23 have to say on the matter, Your Honor.

24 THE COURT: Do you anticipate asking Dr. Schaff

25 opinion questions?

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1 MR. COREN: Well, it's really -- I have to say
2 it's hard to say, you know, where an opinion question is.
3 For example, has he recommended to St. Jude based on
4 Silzone whether to put the valve back on the market? To me
5 that's a fact question, not an opinion question. I gather
6 from the other side, that's an opinion question. That's
7 what I said is, there's where the slippery slope is given
8 what the nature of this witness was retained by St. Jude to
9 do.

10 You know, I don't want to quibble with Ms. Decker
11 of whether you pay Dr. Schaff or you pay Mayo. Dr. Schaff
12 was viewed as a consultant to these people. His name was
13 offered to the FDA and to the medical community as vouching
14 and passing upon the safety of this valve.

15 So I guess the issue is, my questions are going
16 to be what's in the eyes of the beholder, but am I going to
17 ask, Do you think that Silzone caused Mr. Grovatt to
18 sustain an injury or to require medical monitoring? No. I
19 don't intend to ask those questions because he's not our
20 witness, and he hasn't been named as an expert on behalf of
21 St. Jude on the opposite of that issue.

22 THE COURT: Ms. Decker, do you have anything

23 else?

24 MS. DECKER: Yes, Your Honor, if I could just

25 add, having been involved in several of these depositions

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1 of nonparty researchers, but the types of questions that
2 we're concerned about are, for example, in Dr. Schaff's
3 2002 article concerning the study, he -- he documents that
4 in his opinion the cause of the paravalvular leak is
5 unclear.

6 He certainly as a fact witness can read that
7 statement, but any inquiry as to the nature of that opinion
8 and on what he relied in reaching that conclusion is expert
9 testimony.

10 MR. COREN: Go ahead. I apologize.

11 MS. DECKER: I think that our position at the
12 deposition and one of the reasons we're here today is to
13 avoid a deposition where the slippery slope becomes the
14 whole deposition and we're instructing the doctor not to
15 answer or are putting on the record our objection to the
16 opinion questions, but one of the -- one of the problems
17 is, Dr. Schaff is a researcher. His entire -- any opinions
18 that he gives or any conclusions that he reaches or if he
19 is asked about monitoring of patients, it all involves
20 testimony that would be considered expert testimony under
21 Federal Rule of Evidence 702.

22 And we see this deposition as being much more
23 clear if it's either very well defined, the scope of it, or
24 if as a hybrid witness like a treating physician Dr. Schaff
25 is reimbursed for the time he spends in the deposition.

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1 MR. COREN: Your Honor, one point of
2 clarification. In the article Ms. Decker refers to,
3 actually Dr. Schaff postulates that it could be that the
4 silver is interfering with fibroblast growth. I tend to
5 think probing that issue of what he has written is fair
6 game and factual since he chose to publish it.

7 MS. DECKER: We're running into exactly the same
8 problem at the deposition, Your Honor. Our position would
9 be that probing into the basis for that opinion is not
10 factual. What he wrote is factual.

11 THE COURT: Is that the only place he has offered
12 an opinion in writing?

13 MS. DECKER: He has been a coauthor on multiple
14 papers, publications related to the AVERT study, and there
15 would be other -- I use that only by means of illustration,
16 Your Honor. There would be a number of other issues at
17 least as a nonparty I would anticipate Dr. Schaff might be
18 asked about.

19 MR. COREN: Another example in fairness, for
20 example, Your Honor, there is the issue of silver allergy,
21 and one of the things that St. Jude would offer in part of

22 their promotion is that Dr. Schaff and the Mayo Clinic
23 investigated independently the silver allergy, and we would
24 need to probe into what information they had or developed,
25 you know. One, did they do it, or are St. Jude's documents

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1 incorrect? And if it's correct, where do we go from there?

2 So we need to probe into that particular area.

3 Dr. Schaff had, you know, was more than just
4 AVERT, Your Honor. He, you know, was, you know, his
5 consultation as they dealt with the issues that were
6 arising with the MDA, the Medical Device Agency, who was
7 putting pressure on St. Jude, which probably you know
8 brought this issue to light, as well as the issues working
9 with Dr. Bruchart and the study that he did, spans from
10 basically 1997 up to the present, Your Honor.

11 THE COURT: Okay. Well, anything else?

12 Ms. Decker, anything else?

13 MS. DECKER: No, Your Honor.

14 THE COURT: Well, this is what I'm going to do:

15 I'm not sure if we technically have a motion for a
16 protective order here or not. I'm not going to order the
17 plaintiffs' steering committee to pay anything other than
18 the normal fees for a fact witness for this deposition. He
19 is a fact witness in the Court's view in this case.

20 He's not there to offer his opinions, nor is he

21 there to be asked his opinions. I think it's fair to be

22 able to probe the background to his writings. It seems to
23 me that what might be prudent, however, is if, Mr. Coren,
24 if there are some areas that based on our discussion today
25 you feel are going to come close to that line, if you want

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1 to submit that to the Court in advance, I'll take a look at
2 it with Ms. Decker having an opportunity to comment, and we
3 can resolve some of these matters ahead of time.

4 That may also serve to make sure that we stay on
5 the side of inquiring after facts rather than opinions in
6 the deposition.

7 MR. COREN: Okay. Your Honor. It will take me
8 about, you know, a week or so to, you know, gather my
9 thoughts on that because, you know, we have been in the
10 process of preparing for the deposition, that as well as
11 trying to work out some of the kinks in getting the --
12 trying to narrow the volume of documents that Dr. Schaff
13 will have to produce.

14 THE COURT: You may find that there is nothing
15 that you have to submit in advance, but if you think it's
16 coming close and it's likely to raise a substantial
17 objection, I would be happy to review it in advance.

18 MR. COREN: Another alternative, Your Honor, is
19 that if we feel at the end of the dep there was nothing
20 that merits, you know, compensation, that we don't agree,
21 it should be either yourself or Special Master Solum --

22 THE COURT: That would be fine. You can work
23 that out either way.

24 MR. COREN: That would be fine, Your Honor.

25 THE COURT: Anything else?

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1 MS. DECKER: No.

2 MR. COREN: Thank you, Your Honor.

3 MR. KOHN: Thank you, Your Honor.

4 * * *

5 I, Kristine Mousseau, certify that the foregoing
6 is a correct transcript from the record of proceedings in
7 the above-entitled matter.

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11 Certified by:
Kristine Mousseau, CRR-RPR

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Dated: March 14, 2005

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